

**Notice of Allowability**

<b>Application No.</b> 09/598,982	<b>Applicant(s)</b> MAFFITT ET AL.	
<b>Examiner</b> Delia M. Ramirez	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- 1.  This communication is responsive to 7/25/2005.
- 2.  The allowed claim(s) is/are 1-6,9-12,17-25,34-36,43-45 and 54-58.
- 3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All   b)  Some\*   c)  None   of the:
    - 1.  Certified copies of the priority documents have been received.
    - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - 3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

- 4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  - 5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
    - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
- 6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- 1.  Notice of References Cited (PTO-892)
- 2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
- 4.  Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5.  Notice of Informal Patent Application (PTO-152)
- 6.  Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
- 7.  Examiner's Amendment/Comment
- 8.  Examiner's Statement of Reasons for Allowance
- 9.  Other \_\_\_\_\_.

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**DETAILED ACTION**

***Status of the Application***

Claims 1-6, 9-12, 17-25,34-36, 43-45 and 54-58 are pending.

Applicant's amendment canceling claims 7-8, 13-16, 37, 41-42 in a communication filed on 7/25/2005 is acknowledged.

As correctly pointed out by Applicants, claims 54-58 were not included in the list of allowable claims. The Examiner inadvertently omitted these claims from the list of allowable claims.

Submission of corrected Figure 1 in a communication filed on 7/25/2005 is acknowledged. The figure is accepted by the Examiner.

In a telephone conversation with Joseph Leone on 9/12/2005, an agreement was reached to amend claim 1 to place the application in condition for allowance.

***Examiner's Amendment***

1. An informal Examiner's amendment to the specification appears below. This amendment is to update the status of prior application(s), recited in the first sentence of the specification (37 CFR 1.78)
2. Please enter the following amendments to the specification as follows:
3. In page 1, immediately after the title, please insert the following sentence:

This is a Continuation-in-part of application Ser. No. 09/079,970, filed April 15, 1998, now U.S. Patent No. 6274366.

4. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

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5. Authorization for this Examiner's amendment was given in a telephone interview with Joseph Leone on 9/12/2005. This amendment is required to correct the positions within SEQ ID NO: 52 (Figure 1) recited in the claim as indicated in the specification (page 30) as amended on 7/22/2003.

6. Please replace claim 1 as follows:

1. A DNA expression construct comprising, in 5' to 3' order: a promoter, the promoter operationally linked to a secretion signal sequence, the secretion signal sequence operationally-linked to a DNA sequence encoding a proteolytic tryptase as shown in Fig. 1 (SEQ ID NO: 52) having an active site mutation at an amino acid position selected from positions 74, 121, and 224, and wherein the expression construct drives expression of a mature proteolytic tryptase that lacks enzymatic activity in eukaryotic host cells transformed to contain the expression construct, the lack of enzymatic activity due to the active site mutation.

*Reasons for Allowance*

7. The following is an Examiner's statement of reasons for allowance. Although the prior art discloses nucleic acids encoding human tryptases, the Examiner has found no teaching or suggestion in the prior art directed to nucleic acids comprising SEQ ID NO: 8 or nucleic acids encoding mutants of the tryptase of SEQ ID NO: 52 as recited in the claims or tryptases comprising SEQ ID NO: 21, 23, 25, 27, 37, 39, 41 or 43. Therefore, claims 1-6, 9-12, 17-25, 34-36, 43-45 and 54-58 directed to (a) DNA constructs comprising nucleic acids (1) which encode the tryptases of SEQ ID NO: 21, 23, 25, 27, 37, 39, 41 and 43, (2) which encode the tryptase of SEQ ID NO: 52 with mutations at positions 74, 121, and 224, and (3) which comprise SEQ ID NO: 8, (b) a method of producing the tryptases encoded by the DNA constructs, and (c) host cells which recombinantly produce the tryptases encoded by the DNA constructs, are allowable over the prior art of record.

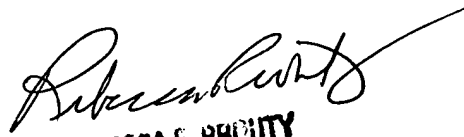
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**Conclusion**

8. Claims 1-6, 9-12, 17-25,34-36, 43-45 and 54-58 are allowed.
9. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.  
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
September 13, 2005

  
REBECCA E. PRODY  
PRIMARY EXAMINER  
GROUP 1800  
1600